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Proposed Registration Decision

CM/LR TT Pheromone Technical

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Overview

Proposed Registration Decision for CM/LR TT Pheromone Technical

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and in accordance with the Pest Control Products Regulations, is proposing full registration for the sale and use of CM/LR TT Pheromone Technical and Isomate-CM/LR TT, which contains the following seven active compounds: (E,E)-8,10-dodecadien-1-ol, 1-dodecanol, 1-tetradecanol, Z-11-tetradecen-1-yl acetate, Z-9-tetradecen-1-yl acetate, Z-11-tetradecen-1-ol, and Z-11-tetradecenal. Isomate-CM/LR TT is proposed for mating disruption of the codling moth and leafroller moths on pome fruit, stone fruit, and tree nut crops.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

This Overview describes the key points of the evaluation, while the Science Evaluation section provides detailed technical information on the human health, environmental and value assessments of CM/LR TT Pheromone Technical and Isomate-CM/LR TT.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (e.g. children) as well as organisms in the environment (e.g. those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties present when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk reduction programs, please visit the PMRA's website at www.pmra-arla.gc.ca.

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1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act.*

2 "Value" as defined by subsection 2(1) of the *Pest Control Products Act* "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact".

Before making a final registration decision on CM/LR TT Pheromone Technical, the PMRA will consider all comments received from the public in response to this consultation document.[3] The PMRA will then publish a Registration Decision document[4] on CM/LR TT Pheromone Technical, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation section of this consultation document.

What Is Isomate-CM/LR TT?

Isomate-CM/LR TT is a slow-release dispenser containing CM/LR TT Pheromone Technical as the active ingredient. CM/LR TT Pheromone Technical contains seven chemical compounds that act as sex pheromones for the codling moth and four species of leafroller moths (obliquebanded, fruittree, threelined, and European leafrollers). Four of the seven chemical compounds in the active ingredient are currently registered in Canadian pest control products. Each of the three new chemical compounds is a part of the sex pheromone for one or more of the four leafroller species. These sex pheromones are produced by female moths and attract male moths for mating.

Health Considerations

Can Approved Uses of Isomate-CM/LR TT Affect Human Health?

CM/LR TT Pheromone Technical is unlikely to affect your health when Isomate-CM/LR TT is used according to label directions.

When assessing the health risks of the product Isomate-CM/LR TT, two key factors were considered: the toxicity of the product and the levels to which people may be exposed.

CM/LR TT Pheromone Technical contains the chemical compounds (E,E)-8,10-dodecadien-1-ol, 1-dodecanol, 1-tetradecanol, Z-11-tetradecen-1-yl acetate, Z-9-tetradecen-1-yl acetate, Z-11-tetradecen-1-ol, and Z-11-tetradecenal, which all belong to a group of compounds known as straight chain lepidopteran pheromones (SCLPs). These pheromones are naturally occurring compounds that are produced by many lepidopteran insect species (i.e. moths and butterflies) to communicate chemically with other members of the same species. In general, SCLPs are biodegraded to non-toxic compounds by enzyme systems that are present in most living organisms. Toxicity studies on SCLPs have generally indicated no mammalian toxicity. The PMRA, United States Environmental Protection Agency and European Union regulatory authorities have received no reports of adverse effects to human health from the use of SCLPs.

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3 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act* (http://laws.justice.gc.ca/en/P-9.01/92455.html)

4 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act* (http://laws.justice.gc.ca/en/P-9.01/92455.html)

Residues in Water and Food

Dietary risks from food and water are not of concern.

Since CM/LR TT Pheromone Technical is unlikely to contact the crop or groundwater because it is contained in a discrete dispenser, the likelihood of residues contaminating food or water is negligible.

Occupational Risks From Handling Isomate-CM/LR TT

Occupational risks are not of concern when Isomate-CM/LR TT is used according to label directions, which include protective measures.

Pesticide applicators using Isomate-CM/LR TT may come in direct contact with the product during application. Therefore, the label specifies that applicators must wear suitable protective clothing, including chemical-resistant gloves and eye protection when handling the dispensers. Taking into consideration these label statements and the low toxicity of this product, the risks to applicators are not of concern.

The risk from bystander exposure or post-application exposure is negligible because CM/LR TT Pheromone Technical is contained in slow-release dispensers that allow the active ingredient to volatilize gradually into the air at rates that are comparable to amounts of pheromone that would be expected during a moth infestation.

Environmental Considerations

What Happens When Isomate-CM/LR TT Is Introduced Into the Environment?

The use of Isomate-CM/LR TT as a mating disruptant poses negligible risk to the environment.

Isomate-CM/LR TT contains CM/LR TT Pheromone Technical, which is released into the environment through passive vapourization into air from fixed dispensers. The SCLP components of the active ingredient belong to a group of chemicals that are naturally based and known to break down rapidly in the environment.

The amount of active ingredient released through the use of Isomate-CM/LR TT is considered comparable to natural emissions and poses a low risk to non-target species. The active ingredient acts as a mating disruptant and does not have a toxic mode of action.

Value Considerations

What Is the Value of Isomate-CM/LR TT?

Isomate-CM/LR TT has value in disrupting the mating of codling moths and obliquebanded, fruittree, threelined, and European leafroller moths, thus reducing the production of larvae that would otherwise damage pome fruit, stone fruit and tree nut crops.

Application of Isomate-CM/LR TT dispensers in pome fruit, stone fruit or tree nut orchards produces numerous artificial sources of sex pheromone, which interferes with the ability of male moths to find females for mating. Females that fail to attract mates cannot lay fertile eggs; therefore, the next generation of larvae is reduced, limiting the damage the larvae would otherwise cause. Combining several pheromone components in a single dispenser creates a product that is effective for mating disruption of all five pest species with a single application.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The risk-reduction measures proposed on the label of Isomate-CM/LR TT are acceptable and no further additional risk-reduction measures are required.

Next Steps

Before making a final registration decision on CM/LR TT Pheromone Technical and the end-use product Isomate-CM/LR TT, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision document, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

Other Information

At the time the PMRA makes its registration decision, it will publish a Registration Decision document on CM/LR TT Pheromone Technical (based on the Science Evaluation section of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

CM/LR TT Pheromone Technical

1.0 The Active Ingredient, Its Properties and Uses

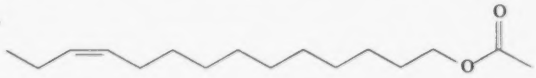
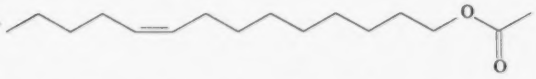
1.1 Identity of the Active Ingredient

Active substance	Z-11-tetradecenal, Z-11-tetradecen-1-ol, Z-9-tetradecen-1-yl acetate, 1-tetradecanol, 1-dodecanol, (E,E)-8,10-dodecadien-1-ol and Z-11-tetradecenyl acetate
Function	Pheromone
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	1. (8E,10E)-dodeca-8,10-dien-1-ol 2. dodecan-1-ol 3. tetradecan-1-ol 4. (11Z)-tetradec-11-en-1-yl acetate 5. (9Z)-tetradec-9-en-1-yl acetate 6. (11Z)-tetradec-11-en-ol 7. (11Z)-tetradec-11-enal
2. Chemical Abstracts Service (CAS)	1. (E,E)-8,10-dodecadien-1-ol 2. 1-dodecanol 3. 1-tetradecanol 4. Z-11-tetradecen-1-yl acetate 5. Z-9-tetradecen-1-yl acetate 6. Z-11-tetradecen-1-ol 7. Z-11-tetradecenal
CAS number	1. 33956-49-9 2. 112-53-8 3. 112-72-1 4. 20711-10-8 5. 16725-53-4 6. 34010-15-6 7. 35237-64-0
Molecular formula	1. $C_{12}H_{22}O$ 2. $C_{12}H_{26}O$ 3. $C_{14}H_{30}O$ 4. $C_{16}H_{30}O_2$ 5. $C_{16}H_{30}O_2$ 6. $C_{14}H_{28}O$ 7. $C_{14}H_{26}O$

Molecular weight

1. 182.3
2. 186.3
3. 214.4
4. 254.4
5. 254.4
6. 212.4
7. 210.4

Structural formula

1.
2.
3.
4. 
5. 
6.
7.

Purity of the active ingredient

(E,E)-8,10-dodecadien-1-ol...39.95% nom. (limits: 38.21–42.33%)
1-dodecanol.....6.21% nom. (limits: 5.31–6.52%)
1-tetradecanol.....1.45% nom. (limits: 1.25–1.65%)
Z-11-tetradecen-1-yl acetate.....39.34% nom. (limits: 38.16–41.50%)
Z-9-tetradecen-1-yl acetate.....4.49% nom. (limits: 3.30–4.90%)
Z-11-tetradecen-1-ol.....1.08% nom. (limits: 0.80–1.30%)
Z-11-tetradecenal.....1.03% nom. (limits: 0.90–1.40%)

1.2 Physical and Chemical Properties of the Active Ingredients and End-Use Product

Technical Product—CM/LR TT Pheromone Technical

Property	Result
Colour and physical state	Light yellow, transparent
Odour	Oily/fatty and slightly waxy
Melting range	N/A
Boiling point or range	A mixture of 1, 2 and 3. 110–120°C at 5.2 mmHg 4. 117°C at 1 mmHg 5. 116–118°C at 130 Pa 6. 138–140°C at 520 Pa 7. 116–122°C at 390 Pa (see Section 1.1 for chemical names of 1, 2, 3, 4, 5, 6 and 7)

Property	Result
Specific gravity	0.872 at 20°C
Vapour pressure at 20°C	A mixture of 1, 2 and 3. 1.428×10^{-2} mmHg at 25°C (1.9 Pa) 4. 7.45×10^{-4} mmHg at 20°C (0.099 Pa) 5. 2.0–2.6 Pa at 20°C 6. 0.16–0.20 Pa 7. 2.0–2.6 Pa at 20°C
Ultraviolet (UV)-visible spectrum	Not expected to absorb UV at $\lambda > 350$ nm
Solubility in water at 20°C	A mixture of 1, 2 and 3. Insoluble in water. 4. Insoluble in water. 5. <0.1 mg/L 6. <0.004 g/L 7. <0.004 g/L
Solubility in organic solvents	A mixture of 1, 2 and 3. Soluble in all common organic solvents. 4. Soluble in n-hexane, cyclohexane, benzene, toluene, methanol, ethanol, acetone, chloroform, acetonitile, dimethyl formamide (DMF), pyridine, aniline. Insoluble in dimethylsulfoxide (DMSO) and ethylene glycol. 5. Soluble in major organic solvents such as: n-hexane, cyclohexene, benzene, toluene, methylene chloride, chloroform, ethyl ether, acetonitrile, tetrahydrofuran (THF) acetone, DMF. 6. Soluble in major organic solvents such as: n-hexane, cyclohexane, benzene, toluene, methylene chloride, chloroform, ethyl ether, acetonitrile, THF, acetone, DMF. Insoluble in DMSO and ethylene glycol. 7. Soluble in major organic solvents such as: n-hexane, cyclohexane, benzene, toluene, methylene chloride, chloroform, ethyl ether, acetonitrile, THF, acetone, DMF. Insoluble in DMSO and ethylene glycol.

Property	Result
n-Octanol–water partition coefficient (K_{ow})	Analyte — K_{ow} A mixture of 1, 2 and 3. >5 4. >6.2 5. >4.0 6. 4.6 7. >4.0
Dissociation constant (p*K*a)	Active ingredient components do not contain dissociable moiety.
Stability (temperature, metal)	Stable under normal conditions, but gradually isomerized and polymerized under sunlight exposure.

End-Use Product—Isomate-CM/LT TT

Property	Result
Colour	Light yellow
Odour	Oily/fatty and slightly waxy odour
Physical state	Liquid
Formulation type	Slow-release generator
Guarantee	(E,E)-8,10-dodecadien-1-ol.....38.62% nom. (limits: 37.46–39.78%) 1-dodecanol.....6.00% nom. (limits: 5.70–6.30%) 1-tetradecanol.....1.40% nom. (limits: 1.33–1.47%) Z-11-tetradecen-1-yl acetate.....38.04% nom. (limits: 36.90–39.18%) Z-9-tetradecen-1-yl acetate.....4.34% nom. (limits: 4.12–4.56%) Z-11-tetradecen-1-ol.....1.05% nom. (limits: 1.00–1.10%) Z-11-tetradecenal.....1.00% nom. (limits: 0.90–1.10%

Property	Result
Container material and description	Ethylene-vinyl acetate copolymer tube contains 2-hydroxy-4-octoxybenzophenone (0.75 ± 0.015%) and Fe_2O_3 (1.8 ± 0.9%), 300 dispenser units per package (each dispenser contains 362.77 mg pheromone)
Specific gravity	0.872 at 20°C
pH of 1% dispersion in water	5.7
Oxidizing or reducing action	The product does not contain any oxidizing or reducing agents.
Storage stability	A one-year storage stability study of the product stored for 12 months at room temperature and at 5°C shows a 1.25% and 0.49% decrease in weight, respectively. The label storage instructions indicate that the unopened package must be stored at a temperature below 4°C in a dry location.
Explodability	Not explosive

1.3 Directions for Use

Isomate-CM/LR TT is for use in pome fruits, stone fruits and tree nut crops to disrupt mating of the codling moth (*Cydia pomonella*), obliquebanded leafroller (*Choristoneura rosaceana*), fruittree leafroller (*Archips argyrospila*), threelined leafroller (*Pandemis limitata*) and European leafroller (*Archips rosana*). Individual Isomate-CM/LR TT dispensers are manually installed on lateral branches in the upper third of the tree canopy at the rate of 750 dispensers (272 g pheromone) per hectare, with the application rate doubled around the edges of a treated orchard. Application timing is in the spring, prior to adult codling moth emergence.

1.4 Mode of Action

The precise mode of action of mating disruption is not completely understood. For example, it may be behavioural, with males being attracted to pheromone dispensers rather than to females; it may be physiological, with the insect nervous system becoming habituated and ceasing to respond to the continuous presence of pheromone in the atmosphere; or it may involve more than one mechanism. In any case, the end result is that males fail to find females for mating and the females can therefore not reproduce. If most females fail to reproduce, the subsequent larval population may be low enough that damage is maintained below economic thresholds.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredient

The methods provided for the analysis of the active ingredient and the impurities in CM/LR TT Pheromone Technical have been validated and assessed to be acceptable for the determinations.

2.2 Method for Formulation Analysis

The method provided for the analysis of the active ingredient in the formulation has been validated and assessed to be acceptable for use as an enforcement analytical method.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

Reduced toxicological data requirements have been established for straight chain lepidopteran pheromones (SCLPs). SCLPs are poorly soluble in water and are biodegradable by enzyme systems present in most living organisms. SCLPs are products of fatty acid metabolism. Health studies have indicated that these substances pose minimal risks and provide effective pest management options at low concentrations, similar to those occurring in nature.

The formulated product, Isomate-CM/LR TT, is contained within a passive, slow-release, discrete dispenser. Therefore, the potential for direct human exposure to the active ingredient is considered negligible.

The applicant provided a rationale that requested all toxicological data requirements be waived because CM/LR TT Pheromone Technical is an SCLP. Also, the impurities and formulants contained in these pest control products are not of toxicological concern. The applicant`s rationale is acceptable and no further toxicological information or data are required.

Based on all of the available data for SCLPs, there is no evidence of increased susceptibility of infants and children in comparison to adults that may result from exposure to SCLPs. Furthermore, there is no evidence that SCLPs have a potential to disrupt endocrine activity in humans.

3.2 Acute Toxicity (technical product and end-use formulation) and Genotoxicity (technical product)

Data submitted to register other SCLPs in Canada and the United States have indicated no mammalian toxicity when mammals are exposed to high doses.

Available data indicate that SCLPs have low acute toxicity (LD_{50} > 5000 mg/kg), low acute dermal toxicity (LD_{50} > 2000 mg/kg), low acute inhalation toxicity (LC_{50} generally >5 mg/L), no evidence of mutagenicity (Ames Salmonella assay), and they generally cause minimal eye and skin irritation. Published mammalian toxicity data on SCLPs indicate no significant acute toxicity to humans. Three of the chemical compounds in CM/LR TT Pheromone Technical have been shown to cause slight-to-moderate dermal irritation in rats, but did not elicit any sensitization response in studies with albino guinea pigs. Consequently, the hazard statement "WARNING - SKIN IRRITANT" is required on the principal display panel of the CM/LR TT Pheromone Technical and Isomate-CM/LR TT product labels. In addition, the following statement is required in the precautions section of both product labels: "Causes skin irritation. DO NOT get on skin."

SCLPs are biodegradable by enzyme systems present in most living organisms. For example, based on the known metabolism of long chain fatty acids, it is predicted that SCLPs would be metabolized either by ß-oxidation yielding a series of paired carbon losses, or by complexing with glucuronide and excretion by the kidneys.

The formulants in Isomate-CM/LR TT are not of toxicological concern.

3.3 Acceptable Daily Intake and Acute Reference Dose Determination

Based on the chemical, physical, biological and toxicological properties of SCLP compounds, it is considered that they pose little or no risk of eliciting any adverse toxicological effects. The data indicate that SCLPs pose a minor potential impact on human or animal health due to their low toxicity and use patterns. Adverse human health effects resulting from exposure to pheromone products have never been reported. Therefore, it is not considered necessary to establish an acceptable daily intake (ADI) or an acute reference dose (ARfD) for CM/LR TT Pheromone Technical due to its inherent lack of toxicity and since it does not pose any significant residue concerns.

3.4 Occupational and Bystander Exposure Assessment

The end-use product is contained in a passive, slow-release, discrete dispenser. The dispensers are manually installed on the branches of trees. One application per year may be made at an application rate of 750 dispensers/ha with double the rate at the edges of orchards.

Based on the toxicological profile of the active ingredient, a quantitative estimate of exposure was not required. Exposure, which is anticipated to be primarily dermal, could occur during installation of the dispensers. The precautionary label statements and required personal protective equipment, i.e. suitable protective clothing, including chemical-resistant gloves and eye protection when handling the dispensers, are adequate to address worker exposure. Bystander and re-entry worker exposure is considered negligible, thus requiring no specific mitigative measures.

Based on the toxicological profile of the active ingredient, it is concluded that use of the end-use product is not likely to present a risk to workers or bystanders when used according to label directions.

3.5 Food Residues Exposure Assessment

CM/LR TT Pheromone Technical is unlikely to contact the crop because it is contained in a discrete, slow-release dispenser. Therefore, contact with food is negligible and the use of Isomate-CM/LR TT would not result in residues that are of toxicological concern to any segment of the population. Consequently, no maximum residue limit (MRL) is recommended for promulgation in Table II, Division B.15.002(1) of the Food and Drugs Regulations.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

As per PRO2002-02, *Guidelines for the Research and Registration of Pest Control Products Containing Pheromones and Other Semiochemicals*, no environmental fate data are required for SCLPs (active ingredients and end-use products).

SCLPs consist of unbranched aliphatic compounds. Breakdown in the environment is rapid, primarily through oxidative processes with enzymes found ubiquitously in nature. Therefore, when Isomate-CM/LR TT is placed in the orchard and the active ingredient is released into the environment, the active ingredient will degrade rapidly. The active ingredient is released through volatilization at a maximum rate considered comparable to natural background levels for SCLPs. The active ingredient is expected to remain as a vapour and degrade rapidly, and is not expected to partition to water, soil or the food materials of non-target organisms.

4.2 Effects on Non-Target Species

As per PRO2002-02, *Guidelines for the Research and Registration of Pest Control Products Containing Pheromones and Other Semiochemicals*, no environmental toxicity data are required for SCLP active ingredients and end-use products if release is through a fixed dispenser.

Based on the application methods (passive release from fixed dispensers into air), expected rapid breakdown, and limited partitioning potential to water or soil, exposure to non-target aquatic and terrestrial organisms in crop areas will be low. Therefore, the proposed use of this product does not pose a concern to non-target organisms.

5.0 Value

5.1 Effectiveness Against Pests

One efficacy trial report was submitted which demonstrated that Isomate-CM/LR TT is effective for mating disruption of the codling moth. No efficacy data were submitted to support the claim for leafrollers; however, an acceptable scientific rationale based primarily on published literature was submitted to justify the expectation of efficacy of Isomate-CM/LR TT for mating disruption of leafrollers. Addition of the three new chemical compounds results in a more complete chemistry that should enhance mating disruption in the four target species of leafrollers. The application rate of 750 dispensers per hectare is very similar, in the amount of active ingredient, to the currently registered application rate of 1000 dispensers per hectare for Isomate-CM/LR Pheromone (Reg. No. 27776).

5.1.1 Acceptable Efficacy Claims

Efficacy data and the submitted scientific rationale support the use of Isomate-CM/LR TT for mating disruption of the codling moth and obliquebanded, fruittree, threelined, and European leafrollers in pome fruits, stone fruits, and tree nut crops at an application rate of 750 dispensers per hectare installed in the spring prior to adult codling moth emergence (see Table 2 in Appendix I).

5.2 Phytotoxicity to Host Plants

Phytotoxicity to host plants was not assessed; however, phytotoxicity is not expected because the active ingredient occurs naturally in the orchard environment and is not applied directly to the trees but is released by volatilization from the dispensers.

5.3 Economics

No economic analysis was conducted for this product evaluation.

5.4 Sustainability

5.4.1 Survey of Alternatives

The availability of alternative insecticides varies depending on the pest and crop. Most insecticide products are registered for use on pome fruits while fewer are registered for use on tree nuts (Appendix I, Table 1). Some of the currently available alternatives are older classes of chemistry (carbamates and organophosphates), which are currently undergoing re-evaluation. Other alternatives include synthetic pyrethroids, neonicotinoids, growth regulators, microbials, mineral oil and kaolin clay. Most of the pheromone components in Isomate-CM/LR TT are also in other products currently registered for use on apples, pears and cherries. However, Isomate-CM/LR TT contains additional leafroller pheromone components and may be used on tree nuts as well as the entire pome fruit and stone fruit crop groups.

5.4.2 Compatibility with Current Management Practices Including Integrated Pest Management

Isomate-CM/LR TT is compatible with current management practices and is particularly well suited to integrated pest management. Due to the non-toxic and species-specific nature of pheromones, they have no direct adverse effects on other pest management strategies, such as the use of beneficial parasites and predators.

5.4.3 Information on the Occurrence or Possible Occurrence of the Development of Resistance

Development of resistance to mating disruption has not been clearly established and the development of resistance to pheromone-based pest management strategies in general is considered unlikely.

5.4.4 Contribution to Risk Reduction and Sustainability

Due to the non-toxic and species-specific mode of action of the active ingredients, Isomate-CM/LR TT should have no direct adverse effects on non-target organisms and may reduce the need for application of conventional insecticides.

6.0 Toxic Substances Management Policy Considerations

The management of toxic substances is guided by the federal government's Toxic Substances Management Policy, which puts forward a preventive and precautionary approach to deal with substances that enter the environment and could harm the environment or human health. The policy provides decision makers with direction and sets out a science-based management framework to ensure that federal programs are consistent with its objectives. One of the key management objectives is virtual elimination from the environment of toxic substances that result predominantly from human activity and that are persistent and bioaccumulative. These substances are referred to in the policy as Track 1 substances.

During the review process, the chemical compounds in CM/LR TT Pheromone Technical: (E,E)-8,10 dodecadien-1-ol (ZAH), 1-dodecanol (ZAG), 1-tetradecanol (ZAF), Z-11-tetradecen-1-yl acetate (ZTE), Z-9-tetradecen-1-yl acetate (ZAD), Z-11-tetradecen-1-ol (ZAC) and Z-11-tetraecenal (ZAA) were assessed in accordance with the PMRA Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*. Substances associated with the use of CM/LR TT Pheromone Technical were also considered, including major transformation products formed in the environment, microcontaminants in the technical product, and formulants in the end-use product Isomate-CM/LR TT. The PMRA has reached the following conclusions:

- It has been determined that CM/LR TT Pheromone Technical does not meet TSMP Track 1 criteria on the grounds of non-persistence, no bioaccumulative potential, and low toxicity.

- CM/LR TT Pheromone Technical does not contain any contaminants of health or environmental concern identified in the *Canada Gazette*, Part II, Volume 139, Number 24, pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern.*

- The end-use product Isomate-CM/LR TT does not contain any formulants of health or environmental concern identified in the *Canada Gazette*, Part II, Volume 139, Number 24, pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern.*

Therefore, the use of CM/LR TT Pheromone Technical and its associated end-use product, Isomate-CM/LR TT, is not expected to result in the entry of Track 1 substances into the environment.

7.0 Summary

7.1 Human Health and Safety

CM/LR TT Pheromone Technical belongs to a class of chemicals, straight chain lepidopteran pheromones (SCLPs), that have been well characterized. SCLPs have been shown to have no mammalian toxicity. They are readily metabolized by most organisms. No adverse health effects of SCLPs have been reported.

Mixers, loaders and applicators are not expected to be exposed to levels of CM/LR TT Pheromone Technical that will result in unacceptable risk when the end-use product is used according to label directions. The personal protective equipment on the product label is adequate to protect workers, and no additional personal protective equipment is required.

CM/LR TT Pheromone Technical is unlikely to contact the crop because it is contained in a discrete, slow-release dispenser. Therefore, contact with food is negligible and use of this product would not result in residues that are of toxicological concern to any segment of the population.

7.2 Environmental Risk

The active ingredients are SCLPs, a group of chemicals that are naturally based and known to break down rapidly in the environment. The active ingredient is released into the environment through passive vapourization into air from fixed dispensers at a maximum rate considered comparable to natural background levels for SCLPs. Partitioning to water or soil is not expected to occur, and exposure to non-target aquatic and terrestrial organisms in crop areas will be low and does not pose a concern.

7.3 Value

Isomate-CM/LR TT has value in disrupting mating of the codling moth and obliquebanded, fruittree, threelined, and European leafroller moths, thus reducing the production of larvae that would otherwise damage pome fruit, stone fruit and tree nut crops.

7.4 Unsupported Uses

All uses were supported as proposed by the applicant, with only minor spelling corrections and wording modifications (see Table 2 in Appendix I).

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act*, is proposing full registration for the sale and use of CM/LR TT Pheromone Technical and Isomate-CM/LR TT containing the following seven active compounds: (E,E)-8,10-dodecadien-1-ol, 1-dodecanol, 1-tetradecanol, Z-11-tetradecen-1-yl acetate, Z-9-tetradecen-1-yl acetate, Z-11-tetradecen-1-ol and Z-11-tetradecenal. Isomate-CM/LR TT is proposed for use in mating disruption of the codling moth and leafroller moths on pome fruit, stone fruit, and tree nut crops. An evaluation of current scientific data from the applicant and information from other regulatory agencies has resulted in the determination that, under the proposed conditions of use, the end-use product has value and does not present an unacceptable risk to human health or the environment.

List of Abbreviations

ADI	acceptable daily intake
ARfD	acute reference dose
C	celsius
CAS	chemical abstracts service
g	gram(s)
ha	hectare(s)
Hg	mercury
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram(s)
K_{ow}	*n*-octanol–water partition coefficient
L	litre(s)
LC_{50}	lethal concentration 50%
LD_{50}	lethal dose 50%
mg	milligram(s)
mm	millimetre(s)
MRL	maximum residue limit
N/A	not applicable
nom.	nominal
nm	nanometre(s)
Pa	Pascal(s)
p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
SCLP	straight chain lepidopteran pheromones

Appendix I Tables and Figures

Table 1 Alternative Insecticides for Supported Uses of Isomate-CM/LR TT

Pest[1]	Crop[2]	Alternative Insecticide Active Ingredients
Codling Moth	Pome Fruits	Carbaryl, Methomyl, Azinphos-methyl, Diazinon, Malathion, Phosalone, Phosmet, Endosulfan, Lambda-cyhalothrin, Cypermethrin, Deltamethrin, Permethrin, Acetamiprid, Thiacloprid, Methoxyfenozide, Tebufenozide, Codling Moth Pheromone ((E, E)-8, 10-dodecadien-1-ol, 1-dodecanol, and 1-tetradecanol), *Cydia pomonella* Granulovirus, Kaolin
	Stone Fruits	Carbaryl, Malathion, Codling Moth Pheromone ((E, E)-8, 10-dodecadien-1-ol, 1-dodecanol, and 1-tetradecanol)
Obliquebanded Leafroller	Pome Fruits	Carbaryl, Methomyl, Azinphos-methyl, Malathion, Phosmet, Lambda-cyhalothrin, Cypermethrin, Deltamethrin, Permethrin, Spinosad, Methoxyfenozide, Tebufenozide, Z-11-Tetradecen-1-yl Acetate (the main component of leafroller pheromones), *Bacillus thuringiensis* subsp. *kurstaki*, Mineral Oil, Kaolin
	Stone Fruits	Carbaryl, Azinphos-methyl, Malathion, Phosmet, Spinosad, Z-11-Tetradecen-1-yl Acetate (the main component of leafroller pheromones), *Bacillus thuringiensis* subsp. *kurstaki*, Mineral Oil
	Tree Nuts	Malathion, *Bacillus thuringiensis* subsp. *kurstaki*, Mineral Oil, Kaolin
Fruittree Leafroller	Pome Fruits	Carbaryl, Azinphos-methyl, Diazinon, Malathion, Lambda-cyhalothrin, Cypermethrin, Deltamethrin, Spinosad, Z-11-Tetradecen-1-yl Acetate (the main component of leafroller pheromones), *Bacillus thuringiensis* subsp. *kurstaki*, Mineral Oil, Kaolin
	Stone Fruits	Carbaryl, Azinphos-methyl, Diazinon, Malathion, Spinosad, Z-11-Tetradecen-1-yl Acetate (the main component of leafroller pheromones), *Bacillus thuringiensis* subsp. *kurstaki*, Mineral Oil
	Tree Nuts	Malathion, *Bacillus thuringiensis* subsp. *kurstaki*, Mineral Oil, Kaolin

Pest[1]	Crop[2]	Alternative Insecticide Active Ingredients
Threelined Leafroller	Pome Fruits	Carbaryl, Malathion, Cypermethrin, Spinosad, Methoxyfenozide, Tebufenozide, Z-11-Tetradecen-1-yl Acetate (the main component of leafroller pheromones), *Bacillus thuringiensis* subsp. *kurstaki*, Mineral Oil, Kaolin
	Stone Fruits	Carbaryl, Malathion, Spinosad, Z-11-Tetradecen-1-yl Acetate (the main component of leafroller pheromones), *Bacillus thuringiensis* subsp. *kurstaki*, Mineral Oil
	Tree Nuts	Malathion, *Bacillus thuringiensis* subsp. *kurstaki*, Mineral Oil, Kaolin
European Leafroller	Pome Fruits	Carbaryl, Malathion, Cypermethrin, Spinosad, Z-11-Tetradecen-1-yl Acetate (the main component of leafroller pheromones), *Bacillus thuringiensis* subsp. *kurstaki*, Mineral Oil, Kaolin
	Stone Fruits	Carbaryl, Malathion, Spinosad, Z-11-Tetradecen-1-yl Acetate (the main component of leafroller pheromones), *Bacillus thuringiensis* subsp. *kurstaki*, Mineral Oil
	Tree Nuts	Malathion, *Bacillus thuringiensis* subsp. *kurstaki*, Mineral Oil, Kaolin

[1] Each species of leafroller is considered to be included in the non-specific claims for "leafrollers."
[2] Listed insecticides may be registered only for specific crops within the indicated crop group.

Table 2 Use Claims Proposed by Applicant and Whether Acceptable

Use Claim	Proposed by Applicant	PMRA Comments
Crops	Apples, pears, quince and other pome fruits; peaches, prunes, plums, nectarines, cherries and other stone fruits; walnut, pecan and other tree nut crops.	Acceptable as proposed.
Pests	Codling moth *(Cydia pomonella)*, obliquebanded leafroller *(Choristoneura rosaceana)*, fruittree leafroller *(Archips argyrospilus)*, threelined leafroller *(Pandemis limitata)*, European leafroller *(Archips rosanus)*.	Acceptable as proposed, with spellings of the respective species names corrected to "*argyrospila*" and "*rosana*."
Application Rate	750 dispensers per hectare (300 dispensers per acre). Apply double rate of dispensers to edges of orchard.	Acceptable as proposed.

Use Claim	Proposed by Applicant	PMRA Comments
Application Timing	Apply prior to codling moth emergence in the spring. Consult a local extension specialist or pest control advisor or Pacific Biocontrol representative for proper timing.	Acceptable as proposed.
Application Method	Place dispensers on lateral branches in upper third of tree canopy.	Acceptable as proposed.
Notes	ISOMATE-CM/LR TT suppresses mating of target pests. Immigration of mated female moths of these species from adjacent orchards will reduce the level of control. Manage by: a. Treatment of external sources of infestation with ISOMATE-CM/LR TT. b. Treatment of external sources of infestation with an effective insecticide. c. Treatment of pheromone-treated orchard with insecticide. Areawide application is most effective. Supplementary applications of insecticide are advised when ISOMATE-CM/LR TT is used in orchards with high pest populations. All pests must be monitored so that timely intervention with insecticides is possible.	Acceptable as proposed, with the term "suppresses" replaced by "reduces" and references to insecticides modified to specify registered insecticides.

List of References

A. LIST OF STUDIES/INFORMATION SUBMITTED BY REGISTRANT

1.0 Chemistry

Technical Grade Active Ingredient

PMRA Identification Number	Reference
1378500	2006, Part 2, Product Chemistry for Registration of a TGAI, DACO: 2.0, 2.1, 2.11.1, 2.11.2, 2.11.3, 2.11.4, 2.12.1, 2.12.2, 2.13.2, 2.13.3, 2.14.1, 2.14.10, 2.14.11, 2.14.12, 2.14.14, 2.14.2, 2.14.3, 2.14.4, 2.14.5, 2.14.6, 2.14.7, 2.14.8, 2.14.9, 2.2, 2.3, 2.4, 2.5, 2.6, 2.7, 2.8, 2.

End-Use Product

PMRA Identification Number	Reference
1369602	2006, Part 3, Product Chemistry for Registration of an EP, DACO: 3.0
1369605	2006, Part 3, Product Chemistry for Registration of an EP, DACO: 3.1.1, 3.1.2
1369608	2006, Part 3, Product Chemistry for Registration of an EP, DACO: 3.1.3, 3.1.4, 3.2.1
1369614	2006, Part 3, Product Chemistry for Registration of an EP, DACO: 3.3.1, 3.3.2
1369620	2006, Part 3, Product Chemistry for Registration of an EP, DACO: 3.4
1369624	2006, Part 3, Product Chemistry for Registration of an EP, DACO: 3.5

2.0 Impact on Human and Animal Health

PMRA Identification Number	Reference
1378548	2006, Part 4, Acute Toxicology Studies of a TGAI, DACO: 4.1, 4.2.1, 4.2.2, 4.2.3, 4.2.4, 4.2.5, 4.2.6, 4.5.4, 4.5.5, 4.5.6
1383360	2006, MSDS-Product, DACO: 0.9
1383362	2006, Comprehensive Data Summary of a TGAI, DACO: 12.7
1369600	2006, Comprehensive Data Summary of an EP, DACO: 12.7
1369635	Part 4, Acute Toxicology Studies of an EP [SUMMARY], DACO: 4.6
1369636	2006, Part 4, Acute Toxicology Studies of a TGAI, DACO: 4.6.1, 4.6.2, 4.6.3, 4.6.4, 4.6.6
1369642	2006, Part 5, Exposure (Occupational and Bystander) of an EP, DACO: 5.1
1369643	2006, Part 5, Exposure (Occupational and Bystander) of an EP, DACO: 5.2
1369582	DACO: 0.9.1

3.0 Value

PMRA Identification Number	Reference
1369592	Isomate CM/LR Twin Tube (TT) 2005 Research: Evaluation of efficacy. 4 pp. DACO 10.2.3.3
1485594	2007. No Title. 19 pp. DACO 10.6

B. ADDITIONAL INFORMATION CONSIDERED

i) Published Information

1.0 Impact on Human and Animal Health

PMRA Identification Number	Reference
1413251	2002, ENVIRONMENT DIRECTORATE, JOINT MEETING OF THE CHEMICALS COMMITTEE AND THE WORKING PARTY ON CHEMICALS, PESTICIDES AND BIOTECHNOLOGY. Guidance for Registration Requirements for Pheromones and Other Semiochemicals Used for Arthropod Pest Control. OECD